

### **REMARKS**

Claims 1-8 are pending in this application. Claims 1, 2 and 5-8 are withdrawn based on an election to a restriction requirement. Claims 3 and 4 stand rejected.

#### **35 U.S.C. § 101 and 35 U.S.C. § 112**

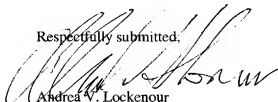
Claims 3 and 4 stand rejected under 35 U.S.C. § 101 because the Examiner alleges that the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility. Specifically, the Examiner concedes that the specification discloses that mRNA encoding SEQ ID NO:2 is expressed in the kidney and peripheral tissue as well as in the CNS. The Examiner also concedes that the specification discloses that HEK293 cells transiently expressing hVR4 were activated by PMA and 4aPDD. However, the Examiner alleges that the specification does not teach any expression data or functional characteristics of the VANILREP4 polypeptide set forth in SEQ ID NO:2. The Examiner alleges that without any biological data or link to disease the application is insufficient to support utility. The Examiner concedes that it is credible that SEQ ID NO:2 is a member of the vanilloid family; however, the Examiner alleges that its identification as an ion channel is not sufficient to establish utility. To support this allegation the Examiner alleges that vanilloid receptors are activated by a diverse range of stimuli, and he cites Gunthorpe, *et al.* (2002) Trends in Pharmacological Science. The Examiner further alleges that because hVR1 and hVR4 are activated by a variety of different stimuli, the specification fails "to disclose the physiological consequence of the activation or any beneficial effect." Finally, the Examiner asserts that if one cannot "predict the effects that the administration of a modulator of the VANILREP4 protein of the instant invention is going to have on an organism, then it is unclear what practical or real world benefit is derived."

The Applicants respectfully traverse this rejection and submit that it is a credible and established utility for a polypeptide to be used for screening for compounds that may act as agonists or antagonists. The Applicants respectfully point out that, as the Examiner concedes, the instant application discloses a vanilloid receptor. In addition, the application also provides, as the Examiner concedes, methods for detecting agonist and antagonists to VANILREP4 polypeptides as well as two examples of an agonists to this receptor. Thus, the application provides sufficient disclosure to meet the requirements for specific, substantial

and credible utility as it describes the use of screening for vanilloid receptor agonists and antagonists using the claimed polypeptide.

The Applicants submit that they have established a legally sufficient utility for the instantly claimed polypeptides. In view of the ample evidence provided above, the Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 3 and 4 under 35 U.S.C. § 101 and 112.

Respectfully submitted,



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